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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,509

Applicant(s)

SHIZUYA, HIROAKI

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 4-9, 11-14 and 17-24 is/are allowed.
- 6) ☒ Claim(s) 3, 10, 15, 16, and 25-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to an amendment filed 11/22/04. Claim 2 has been cancelled. Claims 1, 3, 9, 14-16, 24, 25, 46, 47 and 55 have been amended. Claims 1 and 3-55 are pending in this application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were necessitated by applicant's amendment of the claims, and therefore, this rejection is final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 10, 15, 16, and 25-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 43 are vague and indefinite in that the metes and bounds of "test cells that do not survive subjection to the environmental conditions as having the transposon in an essential chromosomal gene" are unclear. As amended, claims 3 and 43 recite that the gene in the known segment of DNA of the haploid test organism that contains the transposon mutagenized DNA. Cells with the transposon in the essential chromosomal gene from the test organism will survive subjection to an environmental condition as demonstrated in table 1.

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Therefore, it is unclear how to use lack of survival to identify an essential gene when the disrupted essential chromosomal gene is from the test organism. **This is a new rejection necessitated by applicant's amendment.**

Claim 10 is vague and indefinite in that the metes and bounds of "selectively non-permissive" are unclear. It is unclear to what "selectively" is selective towards or against. It would be remedial to delete "selectively" from this claim. **This rejection is maintained for reasons of record in the office action mailed 5/5/04 and restated below.**

Claims 15 and 16 are vague and indefinite in that the metes and bounds of "identified essential chromosomal gene has 80% (90%) sequence identity" are unclear. As amended, the claims recite that the identified essential gene is from the haploid test organism and has 90% or 80% identity with a known segment of DNA from the haploid test organism. As the identified gene and the known segment of DNA are one and the same piece of DNA, it is unclear how the essential gene can have less than 100% identity to itself. **This is a new rejection necessitated by applicant's amendment.**

Claim 25 is vague and indefinite in that the metes and bounds of "suitable" are unclear. The term "suitable" is a relative one not defined by the claim, no single set of conditions is recognized by the art as being "suitable" and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established. **This rejection is maintained for reasons of record in the office action mailed 5/5/04 and restated below.**

Claim 25 is vague and indefinite in that the metes and bounds of "test cells that do not survive subjection to the environmental conditions as containing the transposon in an essential

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chromosomal gene” are unclear. As amended, claim 25 recites, “gene in the known segment of DNA of the pathogenic bacterium inserted into the test cell by the BAC that has been disrupted by the transposon”. Cells with the transposon in the essential chromosomal gene from the test organism will survive subjection to an environmental condition as demonstrated in table 1. Therefore, it is unclear how to use lack of survival to identify an essential gene when the disrupted essential chromosomal gene is from the test organism. **This is a new rejection necessitated by applicant’s amendment.**

Response to Arguments

Applicants traverse the rejections under 35 U.S.C. 112, second paragraph on pages 12-16 of the amendment filed 11/22/04. Applicants indicate that claim 10 has been amended to delete the word “selectively”. However, the amended changes are not found in the claim.

Applicants argue that use of “suitable” is not the least bit vague or confusing. However, use of the term “suitable” is a relative term not defined by the claim, no single set of conditions is recognized by the art as being “suitable” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established. Therefore, the reference by which “a suitable culture medium” is determined to be “suitable” is not known.

Conclusion

Claims 1, 4-9, 11-14 and 17-24 are allowed.

Claims 3, 10, 15, 16, and 25-55 are rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1636

January 26, 2005


GERRY LEFFERS
PRIMARY EXAMINER